

**K113075****510(k) Summary – EmbryoScope (Version D) and EmbryoViewer software**Administrative information:

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Date of summary: 19-Dec-2011

Propose of submission: The propose of this submission is to add the optional accessory EmbryoViewer software.

Device name :

| Trade name   | Common name              | Class | CFR Reference | Procode |
|--|--------------------------|-------|---------------|---------|
| EmbryoScope (Version D) and EmbryoViewer™ software | Embryo monitoring system | II    | 884.6120      | 85 MQG  |

**Indications for Use:**

The EmbryoScope (Version D) provides an environment with controlled temperature, CO<sub>2</sub> (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.

EmbryoViewer is an optional accessory software package for use in displaying, comparing, storing, and transferring EmbryoScope (Version D) generated images. The software includes a user annotation function for capturing information on embryo development parameters, treatment data, and outcome data. The EmbryoViewer software does not control any hardware components in the EmbryoScope (Version D) device.

**Device Description:**

The EmbryoScope™ – (Version D) is an embryo incubator, which performs time-lapse microscopy at multiple planes and logging of incubation conditions on individual embryos during their development. The EmbryoScope (Version D) included in this submission is identical to that cleared in previous 510(k) submissions (K092183 and K111715).

The EmbryoViewer software is an accessory to the EmbryoScope (Version D). The EmbryoViewer™ software does not perform any diagnostics, but only shows data from the EmbryoScope™ (Version D) and data filled in by the user. The EmbryoViewer™ software assists the user by allowing for inspection of high resolution time-lapse images of embryo development, detailed annotation tools and inspection of EmbryoScope™ (version D) running conditions.

**Comparison to Predicate Device:**

Table 1: Comparison of EmbryoScope (Version D) and EmbryoViewer™ software to EmbryoScope (Version D) – K092183 and K111715.

|                            | <b>EmbryoScope (Version D) and EmbryoViewer software</b>   | <b>EmbryoScope (Version D)</b>  |
|----------------------------|--|---|
| <i>Indications for use</i> | <p>The EmbryoScope (Version D) provides an environment with controlled temperature, CO<sub>2</sub> (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.</p> <p>EmbryoViewer is an optional accessory software package for use in displaying, comparing, storing, and transferring EmbryoScope (Version D) generated images. The software includes a user annotation function for capturing information on embryo development parameters, treatment data, and outcome data. The EmbryoViewer software</p> | <p>The EmbryoScope (Version D) provides an environment with controlled temperature, CO<sub>2</sub> (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development.</p> |



|   |  |   |
|---|--|---|
|   | does not control any hardware components in the EmbryoScope (Version D) device.  |   |
| <i>Discussion of NonClinical Tests performed for the determination of Substantial Equivalence</i> | Underwent and passed electrical safety electromagnetic compatibility, environmental and operating performance testing. Classification according to IEC 60601-1. The EmbryoViewer software is fulfilling the requirements of the EN 62304 standard according to software testing. | Underwent and passed electrical safety electromagnetic compatibility, environmental and operating performance testing. Classification according to IEC 60601-1. |

Summary of comparison to predicate device:

*The current submission includes addition of the optional EmbryoViewer to be used with the predicate device The EmbryoScope (Version D). This extension results in a new Indication for Use reflection the addition of annotation tool.*

*The EmbryoViewer software does not introduce changes to the EmbryoScope (Version D) thus the components in this device are identical in the predicate device.*

*As the EmbryoViewer software does not control any functions on the EmbryoScope (Version D) device it can not affect the operation of the EmbryoScope (Version D) device.*

*The purpose of the EmbryoViewer software is to view images generated by the EmbryoScope (version D), and software validation testing has been conducted to verify data transfer.*

*The annotation functions of the device do not raise any concerns because the information inputted by the physician is the same that would typically be collected by an embryologist and maintained on paper patient records. Also, software testing has been conducted to verify correct annotation information for a specific patient/embryo.*

*In the event of a software malfunction, there will be no affect on the EmbryoScope device.*

*Conclusion: The addition of the optional EmbryoViewer software to the EmbryoScope (Version D) does not raise new types of safety and effectiveness questions.*



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
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Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

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DENMARK

DEC 21 2011

Re: K113075

Trade/Device Name: EmbryoScope (Version D) and EmbryoViewer Software  
Regulation Number: 21 CFR§ 884.6120  
Regulation Name: Assisted reproduction accessories  
Regulatory Class: II  
Product Code: MQG  
Dated: October 14, 2011  
Received: October 24, 2011

Dear Dr. Munch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

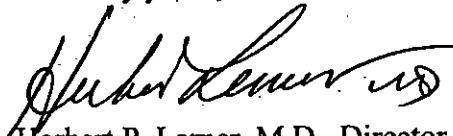
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)  
Division of Reproductive, Gastro-Renal  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K113075

Device Name: EmbryoScope (Version D) and EmbryoViewer software

### Indications For Use:

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

John M. Why  
(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K113075

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